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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/814,257	03/21/01	HANSON	N 180.00030102

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EXAMINER	
LU,F	
ART UNIT	PAPER NUMBER
1655	4

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/814,257	Applicant(s) HANSON ET AL.	
	Examiner Frank W Lu	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17,39-49 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17,39-49 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: please note that the top margin of pages 48-51 of the specification is incorrect. Upon punching holes in the top margin for retention tabs, portions of the first line of text were obliterated. Applicant is required to provide replacement pages with proper margins..

Appropriate correction is required.

Sequence Rules Compliance

2. The original filed sequencing listing in this instant application has complied with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Leegaard *et al.*, (APMIS, 104, 302-306, 1996). .

Leegaard *et al.*, teach the detection an OXA-1 beta lactamase from the blood of patient in Kenya. The presence of the encoding genes such as TEM beta lactamase was confirmed by PCR (see page 302, abstract and right column). Note that at least one base in TEM gene primers was complementary with SEQ ID NOS: 32-43.

Therefore, Leegaard *et al.*, teach the limitations recited by claims 12-16.

5. Claims 12-17 and 39-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Vahaboglu *et al.*, (J. Clin. Microbiology, 36, 827-829, March 1998).

Vahaboglu *et al.*, teach the detection and identification of OXA-10-derived ceftazidime-hydrolyzing extended-spectrum β-lactamases in clinical samples from Turkey. PCR was designed to amplify a 720 bp fragment of OXA-10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and restriction enzymes were used to differentiate different OXA subtypes (see pages 827 and 828 and Figure 1). Note that at least one base in the sense primer or the antisense primers of beta lactamase OXA-10 was complementary with SEQ ID NOS: 32-43.

Therefore, Vahaboglu *et al.*, teach the limitations recited by claims 12-17 and 39-48.

6. Claims 12-17 and 39-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Speldooren *et al.*, (Antimicrobial Agents and Chemotherapy, 42, 879-884, April 1998).

Speldooren *et al.,* teach discriminatory detection of inhibitor-resistant beta-lactamases in *Escherichia coli* from clinical samples by single-stranded conformation polymorphism-PCR. Beta-lactamases TEM and OXA-1 primers were used for PCR (see abstract in page 879 and left column in page 880). A OXA-1 specific PCR product was generated using DNA from Strain 4P4 (see page 882, left column). Note that at least one base in primers A to H was complementary with SEQ ID NOS: 32-43 (see page 828,Table 2).

Therefore, Speldooren *et al.,*teach the limitations recited by claims 12-17 and 39-48.

7. Claims 12-17 and 39-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Siu *et al.,* (APMIS, 106, 917-920, September 1998).

Siu *et al.,* teach to PCR the OXA-1 like enzyme using primers A and B known to be specific for beta lactamase OXA- 1 and -4 (see abstract in page 917 and right column in page 918). Note that at least one base in primers A and B was complementary with SEQ ID NOS: 32-43.

Therefore, Siu *et al.,*teach the limitations recited by claims 12-17 and 39-48.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vahaboglu *et al.*, (1998) as applied to claims 12-17 and 39-48 above, and further in view of Fluit *et al.*, (WO91/08305, published on June 13, 1991).

The teachings of Vahaboglu *et al.*, have been summarized previously, *supra.* The bacteria isolates in Table 1 (page 828) could be considered as the positive and negative controls as described in 49.

Vahaboglu *et al.*, do not disclose a bacteria diagnostic kit.

Fluit *et al.*, do teach a bacteria diagnostic kit (see pages 24 and 25).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized the components and method taught by Vahaboglu *et al.*, into a kit because the method for identifying a beta-lactamase in a clinical sample using PCR was known at that time the inventions were made and the kit format was utilized not only assemble a variety of different reagents together but

ensured the quality and compatibility of the reagents. Fluit *et al.*, would have motivated and suggested the assemblage of reagent (s) of biotechnology methods into a kit in order to obtain the above discussed advantages, thus resulting in instant kit described in claims 49 and 51. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because all of these prior art are known and are easy to use.

Conclusion

10 No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
August 10, 2001

Ethan Whisenant, Ph.D.
Primary Examiner (FSA)